

SPECIAL 510(k): Device Modification
OIVD Review Memorandum (Decision Making Document is Attached)



To: THE FILE

RE: DOCUMENT NUMBER **k103021**

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) **k072369 Evolution Blood Glucose Monitoring System.**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for:

- A. Addition of the speaking function. The speaking function required: a. a software change and b. a labeling change
 - B. The physical appearance of the meter has slightly changed:
 - The battery type has changed from 3.0 V lithium batteries CR2032 to 1.5 V Alkaline Batteries AAA
 - The design of the bottom cover of the meter has slightly changed because the battery type has changed.
 - Weight: from 45g±1 to 69g±1 with batteries
 - Data display and icons for the following features have been additionally included/improved:
 - Voice function
 - Battery type
 - Date indication format has changed from MON. DAY to MTH. DAY.
 - Before having a meal indication format changed from  to 
 - The location of some indicators has changed.
 - C. The name of the device has changed from "Evolution Blood Glucose Monitoring System" to "Element plus Blood Glucose Monitoring System"
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and analytes.
 5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

The ElementTM *plus* Blood Glucose Monitoring System is intended for single patient home use only. CaviWipesTM Disinfecting Towelettes (EPA Reg. No. 46781-8) were validated demonstrating complete inactivation of live hepatitis B virus on materials from the ElementTM *plus* meter and lancing device. Robustness studies were also performed on the meter and the lancing device demonstrating that there was no change in performance or in the external materials of the meter and lancing device after 1,095 cleaning and disinfection cycles designed to simulate one cycle a day, over 3 years of single-patient use.. Each robustness cycle consisted of one pre-clean wipe and one disinfection wipe. The labeling has been revised for adequate instructions on the validated cleaning and disinfection procedures.